CLAIMS

We claim:

1. A method for identifying a cancer patient susceptible to arginine deprivation therapy comprising the steps:

a) obtaining a tumor sample from the cancer patient; and

b) detecting the presence or absence of evidence of *ASS* expression in said tumor sample, wherein the absence of evidence of *ASS* expression in said tumor sample is indicative of a cancer patient who is a candidate for arginine deprivation therapy and the presence of evidence of *ASS* expression in said tumor sample is indicative of a cancer patient who is not a candidate for arginine deprivation therapy.

2. The method of claim 1 wherein prior to, simultaneous with, or after testing the tumor sample, the method further comprises the steps of:

c) obtaining a non-cancerous sample from the cancer patient; and

d) detecting the presence or absence of evidence of *ASS* expression in said non-cancerous sample, wherein the absence of evidence of *ASS* expression in said non-cancerous sample and absence of evidence of *ASS* expression in said tumor sample is indicative of a cancer patient who is not a good candidate for arginine deprivation therapy, wherein the presence of evidence of *ASS* expression in said non-cancerous sample and the absence of evidence of *ASS* expression in said tumor sample is indicative of a cancer patient who is a good candidate for arginine deprivation therapy, and wherein the presence of evidence of *ASS* expression in said tumor sample is indicative of a cancer patient who is not a candidate for arginine deprivation therapy.

3. The method of claim 1 wherein said cancer patient has hepatoma, melanoma, sarcoma, or breast cancer.

4. The method of claim 1 wherein the presence or absence of evidence of *ASS* expression is detected using a technique selected from the group consisting of PCR, Northern blotting, Southern blotting, RNA protection, and DNA hybridization.

5. The method of claim 1 wherein the presence or absence of evidence of *ASS* expression is detected using PCR.

6. The method of claim 1 wherein the presence or absence of evidence of *ASS* expression is detected using a technique selected from the group consisting of Western blotting, ELISA, enzyme assays, slot blotting, peptide mass fingerprinting, electrophoresis, and immunohistochemistry.

7. The method of claim 1 wherein the presence or absence of evidence of *ASS* expression is detected using ELISA.

8. The method of claim 1 wherein the tumor sample is further processed prior to, simultaneously with, or subsequent to said detection of the presence or absence of *ASS* in the sample.

9. The method of claim 1 wherein said tumor sample comprises cells selected from the group consisting of hepatoma, melanoma, sarcoma, and breast cancer cells.

10. A method of treating a patient who has cancer comprising the steps of:

a) determining if the cancer patient is a candidate for arginine deprivation therapy according to claim 1 or claim 2;

b) treating the cancer patient with arginine deprivation therapy if the cancer patient is a candidate for arginine deprivation therapy; and

c) treating the cancer patient with conventional cancer treatment if the cancer patient is not a candidate for arginine deprivation therapy.

11. The method of claim 1 wherein said evidence of *ASS* expression in said tumor sample is detected comprising the steps of:

(a) contacting the tumor sample of said cancer patient with a nucleic acid probe which hybridizes under hybridization assay conditions to a nucleic acid target region of a polypeptide having the sequence of SEQ ID NO:7, said probe comprising the nucleic acid

sequence encoding the polypeptide, fragments thereof, and the complements of the sequences and fragments; and

(b) detecting the binding of said nucleic acid probe to said nucleic acid target region, wherein absence of binding of said nucleic acid probe to said nucleic acid target region from said tumor sample is indicative of a cancer patient who is a candidate for arginine deprivation therapy and the presence of binding of said nucleic acid probe to said nucleic acid target region from said tumor sample is indicative of a cancer patient that is not a candidate for arginine deprivation therapy.

12. The method of claim 11 wherein said nucleic acid probe has a detectable label.

13. The method of claim 12 wherein said detectable label is radioactive, fluorescent, or chromomorphic.

14. The method of claim 13 wherein said detectable label is ^{131}I, ^{125}I, ^{14}C, ^{35}S, ^{32}P, or ^{33}P.

15. The method of claim 13 wherein said detectable label is fluorescein, phycolipoprotein, or tetrarhodamine isothiocyanate.

16. The method of claim 13 wherein said detectable label is an enzyme.

17. The method of claim 13 wherein said detectable label has a visible color.

18. The method of claim 1 wherein said evidence of *ASS* expression in said tumor sample is detected comprising the steps of:

a) contacting the tumor sample of said cancer patient with at least one *ASS*-specific polynucleotide or complement thereof; and,

b) detecting the binding of said *ASS*-specific polynucleotide or complement thereof to a target in said tumor sample, wherein absence of binding of the *ASS*-specific polynucleotide to the target in said tumor sample is indicative of a cancer patient who is a

candidate for arginine deprivation therapy and the presence of binding of the *ASS*-specific polynucleotide to the target in the tumor sample is indicative of a cancer patient who is not a candidate for arginine deprivation therapy.

19. The method of claim 18 wherein said antibody has a detectable label.

20. The method of claim 19 wherein said detectable label is radioactive, fluorescent, or chromomorphic.

21. The method of claim 19 wherein said detectable label is ^{131}I, ^{125}I, ^{14}C, ^{35}S, ^{32}P, or ^{33}P.

22. The method of claim 19 wherein said detectable label is fluorescein, phycolipoprotein, or tetrarhodamine isothiocyanate.

23. The method of claim 19 wherein said detectable label is an enzyme.

24. The method of claim 19 wherein said detectable label has a visible color.

25. The method of claim 1 wherein said evidence of *ASS* expression in said tumor sample is detected comprising the steps of:

a) amplifying a tumor nucleic acid sample of a cancer patient with at least one nucleic acid molecule primer having at least a portion of a nucleotide sequence of SEQ ID NO:1, and

b) determining whether a product of said amplification is homologous to said sequence of SEQ ID NO:1, or portion thereof, wherein homology of said product to said sequence of SEQ ID NO:1 is indicative of a cancer patient who is not a candidate for arginine deprivation therapy and wherein absence of homology between said product and said sequence of SEQ ID NO:1 is indicative of a cancer patient who is a candidate arginine deprivation therapy.

26. The method of claim 25 wherein said nucleic acid molecule primer has a sequence selected from the group consisting of SEQ ID NO:3 or SEQ ID NO:4.

27. The method of claim 1 wherein said evidence of *ASS* expression in said tumor sample is detected comprising the steps of:

a) contacting the tumor sample of the cancer patient with an antibody directed to an *ASS* protein, or portion thereof; and

b) detecting binding of the antibody to said *ASS* protein, or portion thereof, in said tumor sample wherein absence of binding of the antibody to said *ASS* protein is indicative of a cancer patient who is a candidate for arginine deprivation therapy and presence of binding of the antibody to said *ASS* protein in said tumor sample is indicative of a cancer patient who is not a candidate for arginine deprivation therapy.

28. A method for identifying a cancer patient susceptible to arginine deprivation therapy comprising the steps:

a) obtaining a tumor sample from the cancer patient; and

b) detecting the presence or absence of evidence of *ASL* expression in said tumor sample, wherein the absence of evidence of *ASL* expression in said tumor sample is indicative of a cancer patient who is a candidate for arginine deprivation therapy and the presence of evidence of *ASL* expression in said tumor sample is indicative of a cancer patient who is not a candidate for arginine deprivation therapy.

29. The method of claim 28 wherein prior to, simultaneous with, or after testing the tumor sample, the method further comprises the steps of:

c) obtaining a non-cancerous sample from the cancer patient; and

d) detecting the presence or absence of evidence of *ASL* expression in said non-cancerous sample, wherein the absence of evidence of *ASL* expression in said non-cancerous sample and absence of evidence of *ASL* expression in said non-cancerous sample is indicative of a cancer patient who is not a good candidate for arginine deprivation therapy, wherein the presence of evidence of *ASL* expression in said non-cancerous sample and the absence of evidence of *ASL* expression in said tumor sample is

indicative of a cancer patient who is a good candidate for arginine deprivation therapy, and wherein the presence of evidence of *ASL* expression in said tumor sample is indicative of a cancer patient who is not a candidate for arginine deprivation therapy.

30. A method of treating a patient who has cancer comprising the steps of:

a) determining if the cancer patient is a candidate for arginine deprivation therapy according to claim 28 or claim 29;

b) treating the cancer patient with arginine deprivation therapy if the cancer patient is a candidate for arginine deprivation therapy; and

c) treating the cancer patient with conventional cancer treatment if the cancer patient is not a candidate for arginine deprivation therapy.